

# Notice of Allowability

Application No.

10/740,695

Examiner

Vikram P. Sundararaman

Applicant(s)

MILLER ET AL.

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to application 10/740,695 dated Dec 18, 2003.
2. ☒ The allowed claim(s) is/are 1-27.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**DETAILED ACTION**

***Allowable Subject Matter***

1. **Claims 1-27** are allowed.
2. The following is an examiner's statement of reasons for allowance:

**Claim 1:**

It is well known in the art to employ non-invasive systems and methods to sense of skin temperature and conductance representative of skin temperature and level of perspiration of a diabetic individual, which are two common criteria used to detect hypoglycemic events in diabetes individuals. It is also well known in the art to include an alarm means responsive to temperature and/or conductance signals based on perception of the presence of a hypoglycemic event based on the same temperature and/or conductance signals. (Potts et al., US 2005/0106709; Johnson, US 4365537; Ward, US 4509531 and McNamara, US 4178531). Furthermore, Semler et al, US Patent Publication 2005/0101875 A1, teaches a non-invasive body composition monitor, and method wherein "...a calculated body composition may be compared to previously recorded or downloaded baseline measurements to determine change and rate of change, thereby to document and record trends that might indicate dehydration or other conditions of concern. It also may be compared to previously recorded or downloaded baseline measurements to determine change and rate of change, thereby to document and record trends that might indicate adverse health status" (Paragraph [0129]).

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It is also well known in the art to establish an alarm in response to signals outside of a threshold. The threshold system in the prior art (Potts, Johnson, and Ward) establish threshold, which are predetermined. What the prior art does not teach is "...a threshold system responsive to the conductance signal and to the temperature signal for producing a slope threshold representative of a hypoglycemic decline in skin temperature observed over the predetermined interval." By way of this threshold system, the present invention improves on the prior art, which use only invariant threshold levels.

**Claims 2-11:**

Claims 2-11 are allowed since they are dependent upon Claim 1, which is allowable as detailed previously in this action.

**Claim 12:**

It is well known in the art to employ non-invasive systems and methods to sense of skin temperature and conductance representative of skin temperature and level of perspiration of a diabetic individual, which are two common criteria used to detect hypoglycemic events in diabetes individuals. It is also well known in the art to include an alarm means responsive to temperature and/or conductance signals based on perception of the presence of a hypoglycemic event based on the same temperature and/or conductance signals. As discussed previously what the prior art does not teach is "...a threshold system responsive to the conductance signal and to the temperature

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signal for producing a slope threshold representative of a hypoglycemic decline in skin temperature observed over the predetermined interval.” By way of this threshold system, the present invention improves on the prior art, which use only invariant threshold levels.

**Claims 13-18:**

Claims 13-18 are allowed since they are dependent upon Claim 12, which is allowable as detailed previously in this action.

**Claim 19:**

Claim 19 is allowed based on the reasons for allowance as relates to Claims 1 and 12, and Claim 19 is a combination of these claims.

**Claims 20-24:**

Claims 20-24 are allowed since they are dependent upon Claim 19, which is allowable as detailed previously in this action.

**Claims 25 - 27:**

Claims 26, 26, and 27 are method claims, which follow the systems described in the systems of Claims 1, 12, and 19 respectively and their dependent claims as discussed above in this action.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Conclusion**

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571-272-3351. The examiner can normally be reached on M-F, 730am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner  
GAU 3736



2023/01/10  
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